DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 11 1985

Re: New Jersey Meniscal
Bearing Knee Replacement
Docket# 85E-0296

The Honorable Donald J. Quigg
Commissioner of Patents
and Trademarks, Designate
Washington, D.C. 20231

Dear Commissioner Quigg:

This is in regard to the application for patent extension for U.S. Patent No. 4,309,778, filed by Biomedical Engineering Trust, under Title II of Public Law 98-417, 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for the New Jersey Meniscal Bearing Knee Replacement, the medical device claimed by the patent.

The total length of the regulatory review period for the New Jersey Meniscal Bearing Knee Replacement is 1701 days. Of this time, 1095 days occurred during the testing phase of the regulatory review period and 606 days occurred during the approval phase. These periods of time were derived from the following information:

1. The date a clinical investigation was begun: August 16, 1980.

   The applicant claimed July 14, 1980 as the date which commenced the testing phase. FDA received the application for an investigational device exemption on July 17, 1980. On August 16, 1980, thirty days after the application was received, it was automatically approved under 21 C.F.R. 812.30(a)(1) (IDE G80-0087).

2. The date the application was initially submitted under subsection 515 of the Federal Food, Drug, and Cosmetic Act: August 16, 1983.

   The applicant claimed that the premarket approval applications for the product (PM30055 and PM30055/S2) were submitted on August 12, 1983. However, FDA received the applications on August 16, 1983.

3. The date the application was approved: April 12, 1985.

The applicant claimed that its product was approved on April 25, 1985. FDA has determined, however, that the premarket approval application (PM30055) and its supplement (PM30055/S2), which cover both parts of the New Jersey Meniscal Bearing Knee Replacement, were approved on April 12, 1985.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

for Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: John G. Gilfillian III
Carella, Byrne, Bain, and Gilfillian
6 Becker Farm Road
Roseland, NJ 07068